

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Altenschopfer et al.

Title: TRANSDERMAL
GRANisetron

Appl. No.: 10/544,259

Filing Date: 12/9/2005

Examiner: Tran, Susan T.

Art Unit: 1618

Confirmation 1348
Number:

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. §1.705

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request reconsideration of the Patent Term Adjustment (PTA) determined for the captioned patent application.

The Patent Office determined that the patent was entitled to 373 days of PTA. Applicants believe that this PTA determination was made in accordance with the "Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. §154(b)(2)(A)" published at 69 Fed. Reg. 34238 (Jun. 21, 2004). Under that interpretation of the PTA statute, any PTO delay under 35 U.S.C. § 154(b)(1)(A) is deemed to overlap with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B), and so, as a practical effect, PTA may be awarded under §154(b)(1)(A) or §154(b)(1)(B), but not both.

On September 30, 2008, the United States District Court for the District of Columbia issued a decision finding that the U.S. Patent and Trademark Office's interpretation of the PTA statute is incorrect. *Wyeth v. Dudas*, Civ. Action No. 07-1492 (JR) (Sep. 30, 2008). The court

determined that, under the correct interpretation of the PTA statute, periods of “overlap” are limited to “periods of time . . . [that] occur on the same day.” *Wyeth*, slip op. at 8. Thus, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays “occur on the same day.” *Id.*

Applicants have recalculated PTA for the captioned application under the court’s interpretation of the PTA statute, and have determined that the patent is entitled to 466 days PTA, as shown on the attached sheet, which shows the relevant delays under 37 CFR §§1.702(a) and (b), and under 37 CFR §§1.703(a) and (b).

The attached sheet details the circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

(a) Total of non-overlapping PTO delay under §154(b)(1)(A) & (B): 496 days

(b) Total Applicant delay: 30 days

Final PTA Determination: 466 days

Applicants therefore respectfully request that the patent be accorded 466 days PTA.

The patent is not subject to a terminal disclaimer.

Payment of the requisite fee is submitted herewith. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

However, because this PTA error is due to a Patent Office error in interpreting and applying the PTA statute, a refund of the fee is respectfully requested.

Applicants request further that a decision on this request be deferred or delayed until a final decision has been rendered in *Wyeth v. Dudas*, which is now on appeal at the U.S. Court of Appeals for the Federal Circuit, under Federal Circuit Docket No. 2009-1120.

Respectfully submitted,

Date 7/14/09

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Patent Term Adjustment Calculation System

Docket Number: 041376-0801
 Application Number: 10/544259
 Patent Number: N/A

	Event Description	Event Date	Days from Filing	PTO Days	Applicant Days
Edit Delete	Priority Date	02/05/2003	-912		
Edit Delete	International Filing Date	02/05/2004	-547		
	PCT National Stage Commencement Date	08/05/2005	0		
Edit Delete	Notice to File Missing Parts	11/21/2005	108		
Edit Delete	National Stage Entry (All 371(c) Requirements Met)	12/09/2005	126		
Edit Delete	Response to Notice to File Missing Parts	12/09/2005	126		
Edit Delete	Application Is Now Complete	12/24/2005	141		
Edit Delete	IDS NOT falling under 1.704(c)(6), (8) or (10) filed at PTO	04/07/2006	245		
Edit Delete	Preliminary Amendment under 1.704(c)(6) Received at PTO	01/24/2007	537		
	14 month From Application date	02/09/2007	553		
Edit Delete	Non-Final Office Action	03/18/2008	956	403	
Edit Delete	Non-Final Office Action Rsp. Rcv'd at PTO	04/02/2008	971		
Edit Delete	Final Office Action	07/07/2008	1,067		
	3 Year Period Starts	08/05/2008	1,096		
Edit Delete	Advisory Action	09/30/2008	1,152		
	Final Office Action + 3 months	10/07/2008	1,159		
Edit Delete	Request For Continued Examination (including amendment)	11/06/2008	1,189	93	30
	3 Year Period Stopped	11/06/2008	1,189		
Edit Delete	Non-Final Office Action	03/06/2009	1,309		
Edit Delete	Non-Final Office Action Rsp. Rcv'd at PTO	03/20/2009	1,323		
Edit Delete	Notice of Allowance	06/24/2009	1,419		
	Projected Patent Grant Date	01/05/2010	1,614		
Totals:				496	30
PTA:				466	

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